

REMARKS

Upon entry of the present amendment, claims 1, 4-6 and 15 will be canceled without prejudice or disclaimer of the subject matter recited therein, whereby claims 7-14 will remain pending.

Reconsideration of the rejection and allowance of the application in view of the following remarks are respectfully requested.

Information Disclosure Statement

Applicants express appreciation for the Examiner's confirming consideration of documents cited in Applicants' Information Disclosure Statement, filed February 24, 2006, and for confirming consideration of the Supplemental Information Disclosure Statement, filed September 10, 2008, by including initialed copies of the Forms PTO-1449 with the Office Action.

Response To Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 1, 4 and 5 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

In response to the ground of rejection, Applicants note that claims 1, 4 and 5 have been canceled in the present response, whereby this ground of rejection is moot. However, Applicants' preserve their right to address this ground of rejection if the canceled subject matter is submitted in this or another application, such as in one or more continuation and/or divisional applications.

Accordingly, withdrawal of the rejection of record is respectfully requested.

Response to Art Based Rejections

The following rejection is set forth in the Final Office Action.

Claims 1 and 4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,503,527 to Whitmore et al. (hereinafter "Whitmore") in view of Suzuki et al. (hereinafter "Suzuki"), *Ionics*, Vol. 25, No. 1, pp. 47-54 – with the provided English language translation being referenced by page and line number in the rejection).

In this ground of rejection, it is contended that Whitmore discloses at column 3, line 14, the use of fibrin adhesive composition to anchor dural patches, and that one having ordinary skill in the art would have used the artificial dura material of Suzuki as the dural patch of Whitmore because it exhibits improved cell attachability and thus would be expected to result in a stronger bond with the fibrin glue composition.

In response to this ground of rejection, Applicants submit that Whitmore relates to a substance which is obtained by chemically immobilizing fibrin-constituting component, such as fibrinogen to hyaluronic acid, chitin or chitosan. Whitmore does not teach or suggest a polymer to which fibrin glue is adhered being formed by irradiation of ion beam.

In particular, Whitmore discloses beginning at column 2, line 45, that his invention relates to a fibrin glue composition comprised of a biocompatible, bioabsorbable hyaluronic acid derivative material, having applied thereto fibrinogen and thrombin. Beginning at column 2, line 62, Whitmore discloses that when placed on a wound site and activated, the compositions of his invention function as a fibrin glue, and that in contrast to conventional fibrin glues, his compositions do not require complex mixing of fibrinogen and thrombin components immediately prior to use and do not

require special applicators. Beginning at column 4, line 10, Whitmore also discloses that his invention contemplates the use of chitin, chitosan and derivatives thereof.

Still further, as recited in claim 1, Whitmore is directed to a fibrin adhesive or sealant composition comprising fibrinogen, a fibrinogen-cleaving agent and a biomaterial which is a hyaluronic acid material, a chitin material or a chitosan material wherein both the fibrinogen and the fibrinogen-cleaving agent are incorporated on the biomaterial.

Whitmore also discloses uses of his compositions at the top of column 3, wherein it is disclosed that the compositions of his invention can be put to a wide range of suitable medical and surgical uses, and that the compositions can be used in hemostasis applications, as sealants and as adhesives. Moreover, it is disclosed that the compositions of his invention have a number of surgical uses, including, in cardiovascular surgery, they can be used as a hemostatic, for example, with needle holes, suture lines, diffuse and nonspecific bleeding, friable tissue bleeding, aortic dissections, ventricular ruptures, and fistulas. In otorhinolaryngology (ear, nose and throat, ENT) surgery, it is disclosed that they can be used in facial nerve grafts, closure of dural leaks, nasal septal surgeries, and post tonsillectomy hemorrhage. In neurosurgery, it is disclosed that they can be used to prevent cerebral spinal fluid (CSF) leakage, peripheral nerve repair, and to anchor dural patches. In plastic surgery, it is disclosed that they can be used in a number of procedures relating to skin grafts, including to fix grafts, control oozing and control bleeding. In thoracic surgery, they can be used, for example, in the treatment of pneumothorax and pulmonary leaks. The compounds of Whitmore's invention are also disclosed to have a number of other surgical uses, including, sealing biopsy needle tracks, liver and splenic lacerations, lymphatic fluid leaks, organ resectioning, seroma and hematoma prevention, and gastrointestinal bleeding. Whitmore also discloses that his compositions can be used

as a local delivery vehicle for the delivery antibiotics or other biologically active substances to the application site. Whitmore also discloses that his compositions may serve as a surgical adhesion barrier, and that other uses are known in the art or will be apparent to the skilled artisan.

Thus, as the rejection realizes, amongst a multitude of uses, Whitmore broadly discloses use of a dural patch, but does not disclose a dural patch as recited in Applicants' claims. In this regard, Applicants' independent claim 7 is directed to a method for improving affinity with a fibrin glue of a polymeric material comprising carbon or silicon as a constitutional element comprising irradiating at least a portion of a surface of the polymeric material with ions to form an ion-modified polymeric material; and applying the fibrin glue to the irradiated at least a portion of a surface of the polymeric material.

In an attempt to overcome this deficiency of Whitmore, the rejection relies upon Suzuki (which includes as an author Yoshiaki Suzuki who is one of the inventors of the presently claimed subject matter). However, one having ordinary skill in the art would not have combined these diverse disclosures. Suzuki discloses that cells are adhered to a polymer which was irradiated with ion beam, and its adhesion strength is improved by irradiation of the ion beam. As disclosed, in Suzuki, such as beginning at page 7, 2.3 Cell culturing method, the cells are cultured *in vitro*, and the cells are selectively adhered to the polymer which was irradiated with the ion beam. In such an "*in vitro*" experiment of cell culturing, the culture solution which contains cells does not contain fibrinogen. The culture solution contains amino acid and serum, which is plasma where fibrinogen is removed. From the results of the *in vitro* experiment of Suzuki, one having ordinary skill in the art would not be capable of predicting that fibrinogen, which is one component of fibrin glue, is adsorbed to a polymer which was irradiated with an ion beam.

Applicants note that the main component of serum is albumin (45%). Based upon the disclosures, even if for the sake of argument the documents were combined, adsorption of albumin may be predicted, but adsorption of fibrinogen would not be predicted. In this regard, prediction based upon an experiment in the absence of fibrinogen is without any support as to any expectation of results with fibrinogen.

Accordingly, Applicants submit that the one having ordinary skill in the art would not have arrived at the subject matter recited in Applicants' claims and/or the results as disclosed by Applicants.

Based on the above, it is respectfully submitted that this application is in condition for allowance, and a Notice of Allowance is respectfully requested.

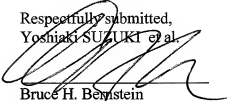
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the objection and rejections of record, and allow each of the pending claims.


Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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